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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,452

08/29/2005

Mitsuru Shiraishi

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05/05/2009

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EXAMINER

CHANG, CELIA C

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/05/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,452	SHIRAISHI ET AL.	
	Examiner	Art Unit	
	Celia Chang	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 February 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-9 and 11-33 is/are pending in the application.
- 4a) Of the above claim(s) 11 and 15-26 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-8, 12-14, 27-33 is/are rejected.
- 7) ☒ Claim(s) 9 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Feb. 5, 2009 have been entered and considered carefully.

Claims 1-6 and 10 have been canceled. Claims 11, 15-26 stayed withdrawn. Claims 7-9, 12-14, and newly added claims 27-33 are pending.

2. The rejection of claims 1-2, 4-6 and 12-14 under 35 USC 112 second paragraph is dropped in view of the cancellation and amendment of the claims.

3. The rejection of claims 1-8, 10, 12-14 under 35 USC 112 first paragraph is maintained for the pending claims 7-8, 12-14.

Please note that while the amended claims 7-8, 12-14 find enabling support for the amended scope of R^7-R^{13} , does not reasonably provide enablement for Z^1 or Z^2 when it is "a carbon atom substituted with a C_{1-4} alkylenedioxy group". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Please note that when either one or both Z^1 or Z^2 is "a carbon atom substituted with a C_{1-4} alkylenedioxy group" they are spiro-compounds for which starting material and how to make or use such compounds are not found but required in the specification. Not a single spiro compound was found in the specification nor any bi-spiro-compounds. Therefore, the 112 first paragraph is maintained for such scope.

4. The newly added claims 27-33 are rejected under the following new grounds of rejection.

Claims 27-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for androgen receptor agonists, does not reasonably provide enablement for "androgen modulator". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

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Please note that the term “modulating” encompassed both up-regulation and down-regulation for which a single compound cannot perform both activity.

The term “agent” is ambiguous and confusing. Please note that it is not clear what does an “agent” mean. Does it mean a compound? Does it mean a compound in a composition? Or Does it mean that a compound when it has androgen receptor agonistic activity? Which means it is a process of treating. Therefore, the claims are considered “hybride” format including compound or composition and its use. It is recommended that the claims be limited to one category of invention i.e. either compound/composition or method of treating.

Any “prevention” must be supported with factual evidence of de novo prevention. Please note that a maintenance dose to prevent symptom or pathology is considered a maintenance treatment. In addition, treating LHRH agonist resistant cancer does not support the scope of treating all hormone resistant cancer since the compounds only have activity being androgen agonists. Treating osteoporosis requires that one who has been diagnosed with osteoporosis (loss of 30% of bone mass) to be reversed of the physiology. Therefore, evidence supporting increasing bone density must be required. The specification provided mere provided AR binding inhibition test and PSA production test (p.253-255) which are not sufficient in supporting treating all hormone resistant cancer or increasing bone density.

5. Claim 9 stayed being objected.

Applicants’ amendment necessitated the new grounds of rejections.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang, Ph. D. whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres, Ph. D., can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
May 4, 2009

/Celia Chang/
Primary Examiner
Art Unit 1625